

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Stamm et al**

Application No. **10/665,522**

Group Art Unit: **1615**

Filed: **September 22, 2003**

Examiner: **Sheikh**

For: **Fenofibrate Compositions Having Enhanced Bioavailability**

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Information Disclosure Statement

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form. A copy of the Non Patent Literature Documents and the Foreign Patent Documents is attached hereto.

Applicants direct the Examiner's attention to:

- (a) Cite No. 1 on PTO-1449 Form No. 1 of 9, the dissolution profile on page 12 at Table VII in Laboratoires Fournier's undated document entitled "Fenofibrate Tablets 54-160 MG Dissolution Test Conditions Development Studies, Dissolution Test Specification Recommendations."
- (b) Cite No. 24 on PTO-1449 Form 3 of 9, the Declaration under 37 CFR § 1.132 by Phillippe Reginalt filed in US Application No. 10/288,425 on March 7, 2005.
- (c) *In re TriCor Indirect Purchaser Antitrust Litigation*, District of Delaware, Civil Action No. 05-360.
- (d) *CVS Pharmacy, Inc. et al. v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00605-KAJ.
- (e) *Walgreen Co. et al v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00404-KAJ.
- (f) *Pacificare Health Systems, Inc. v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00591-KAJ.

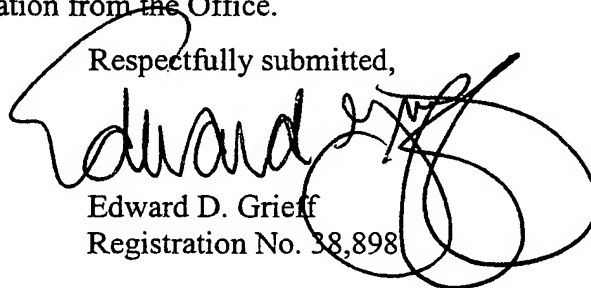
- (g) *Painters District Council No. 30 Health and Welfare Fund et al v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00360-KAJ.
- (h) *Louisiana Wholesale Drug Company, Inc. v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00340-KAJ;
- (i) *Paul T. Tegan v. Abbott Laboratories et al*, Central District of California, 2:05-cv-05410-GAF-AJW.

The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents, oppositions and/or litigations are material to patentability or that the listed documents are prior art.

This Information Disclosure Statement is being filed after the mailing date of a first office action on the merits, but before a final office action or a notice of allowance. Accordingly, the Commissioner is authorized to charge the fee of \$180 to Deposit Account No. 22-0261. The Commissioner is authorized to charge any other necessary fees or credit any overpayments to Deposit Account No. 22-0261.

Applicants respectfully request that the PTO return an initialed copy of the PTO-1449 Form with the next communication from the Office.

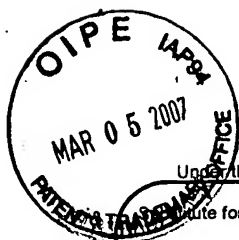
Respectfully submitted,



Edward D. Grieff
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Date: May 8, 2006

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PTO/SB/08B (07-05)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known	
		Application Number	10/665,522
		Filing Date	September 22, 2003
		First Named Inventor	Stamm
		Art Unit	1615
		Examiner Name	Sheikh
		Attorney Docket Number	224622

Sheet	1	of	4
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	Laboratoires Fournier undated document entitled "Fenofibrate Tablets 54-160 mg Dissolution Test Conditions Development Studies, Dissolution Test Specification Recommendations"	
	2	"Second Amended Answer, Affirmative Defenses, and Counterclaims" filed by Teva on 7-29-2005 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc. DE, CA No. 02-1512.	
	3	"First Amended Counterclaims" filed by Impax on 9-23-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	4	"Amended Complaint" filed by CVS Pharmacy et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	5	"Amended Complaint" filed by Walgreen Co. et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	6	"Amended Complaint" filed by Painters' District Council No. 30 et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	7	"Amended Complaint" filed by Louisiana Wholesale Drug Co. et al on 10-3-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	8	"Defendant's Responses to Plaintiffs Interrogatories" filed by Impax on 8-6-2003 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	9	"Amended Answer" filed by Impax on 1-4-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	10	"Reply Memorandum" filed by Impax on 2-25-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number 10/665,522

Filing Date September 22, 2003

First Named Inventor Stamm

Art Unit 1615

Examiner Name Sheikh

Sheet 2

of

4

Attorney Docket Number 224622

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	11	"Memorandum Opinion" by District Judge Jordan dated 5-6-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	12	"Opening Brief in Support of Motion for Summary Judgment" by Teva filed on 12-23-2004 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512.	
	13	"Opening Brief in Support of Motion for Summary Judgment" by Teva filed on 12-10-2004 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512.	
	14	"Memorandum Opinion" by District Judge Jordan dated 5-6-2005 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512.	
	15	Opposition to European Patent No. 1 273 293 filed 9-2-2005 by Ethypharm (French Language Document).	
	16	Opposition to Israel Patent No. 130790 filed 5-4-2005 by Teva; and Remarks in Response to Opposition filed on 9-23-2005 (English language translations).	✓
	17	Munoz et al, Atherosclerosis, 110(Suppl.):S45-S48 (1994).	
	18	Pharmaceutical Pelletization Technology, Marcel Dekker, Inc., Volume 37, pages 1-13; 160-161; and 234-235 (1989).	
	19	Modern Pharmaceutics, Third Edition, Marcel Dekker, Inc., pages 131-133 and 335-356 (1996).	
	20	Pharmaceutical Dosage Forms, Tablets, Second Edition, Marcel Dekker, Inc., pages 5-28; 88-107; 133; 142; 160-165; and 260-267 (1989).	

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Sheet 3 of 4	Application Number	10/665,522
	Filing Date	September 22, 2003
	First Named Inventor	Stamm
	Art Unit	1615
	Examiner Name	Sheikh
Attorney Docket Number		224622

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	21	Shepherd Atherosclerosis, 110(Suppl.)S55-S63 (1994).	
	22	Adkins et al, Drugs, 54(4):615-633 (October 1997).	
	23	Letter from Teva/Novopharm to Fournier Pharma Inc. regarding Invalidity and Ambiguity of Canadian Patent Nos. 2,219,475 and 2,372,576 (pages 1-15)(September 19, 2005).	
	24	Declaration under 37 CFR 1.132 by Phillippe Reginault filed in US Application No. 10/288,425 on March 7, 2005.	

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Sheet	4
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of 4

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[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ² Number ⁴ Kind Code ⁵ (if known)				
		CA 2,142,848	03-17-1994	Janssen Pharmaceuticals		
		CA 960,670	01-07-1975	Orchiméd SA		
		WO 98/31360	07-23-1998	Pharma Pass		
		WO 97/12581	04-10-1997	Pharma Pass		
		CA 2,219,475	07-09-2002	Laboratoires Fournier		
		CA 2,372,576	02-10-2004	Laboratoires Fournier		

**Examiner
Signature**

Date
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Respectfully submitted,

Edward D. Grieff
Registration No. 38,898

Date: June 19, 2006
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Washington, DC 20004
Phone: 202-344-4382

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		Opposition to European Patent No. 1 273 293 filed 9-2-2005 by Ethypharm. (English Language Translation)	✓
		Laboratoires S.M.B. S.A. Report pages 1-4 (undated)	
		Report from Pr. Rosset entitled "La biodisponibilite du fenofibrate et les polymeres hydrophiles," Pages 1-20 (March 1, 2005)	

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